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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/016,869	01/30/98	BEACH	071.10

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1644	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/016,869	Applicant(s) Beach, et al.
	Examiner Mary Tung	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Jul 12, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 10, 11, and 58-76* is/are pending in the application.

Of the above, claim(s) *1 and 10* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11 and 58-76* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Since Applicant desires priority under 35 U.S.C. 119, based upon previously filed copending applications, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. It is acknowledged that the Applicants have included the U.S. application numbers in the amendment filed 12/7/98, Paper No. 4, however, the Applicants are requested to update the status of all applications. Additionally, lines 6-16, the first paragraph of page 1 need to be cancelled, since Paper No. 4 provides duplicate information. Also, the claim to priority to PCT/US93/09945, filed 10/18/93, disclosed in the Oath/Declaration, needs to be included in the paragraph.

2. Acknowledgment is made of Applicant's claim for foreign priority based on the PCT/US93/09945 application filed 10/18/93. It is noted, however, that Applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

Sequence rules:

3. The specification on pages 4 and 5 in the "Brief Description of the Drawings" (Figures 1A, 1B, 2A-2C, 3A-3C and Figure 6 (p16, p15, and p13), and pages 9, 10 and 28 are objected to under *37 C.F.R. 1.821(d)* for failing to disclose and recite the Sequence ID number.

CRF in Parent:

4. This application fails to comply with *37 C.F.R. 1.821-1.825* because there was no submission of a Sequence Listing. The search of the recited sequences was conducted based upon the Sequence Listing and CRF submitted in the parent application, # 08/893,274. The Applicants are required to either submit a new sequence listing and a new CRF or a letter authorizing the use of the sequence listing filed with the prior application, along with a statement that the sequences in the two cases are identical.

37 C.F.R. 1.821 (e) A copy of the "Sequence Listing" referred to in paragraph (c) of this section must also be submitted in computer readable form in accordance with the requirements of § 1.824. The computer readable form is a copy of the "Sequence Listing" and will not necessarily be retained as part of the patent application file. **If the computer readable form of a new application is to be identical with the computer readable form of another application of the Applicant on file in the Office, reference may be made to the other application and computer readable form in lieu of filing a duplicate computer readable f rm in the new application. The new application**

shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified.

(f) **In addition to the paper copy required by paragraph (c) of this section and the computer readable form required by paragraph (e) of this section, a statement that the content of the paper and computer readable copies are the same must be submitted with the computer readable form. Such a statement must be a verified statement if made by a person not registered to practice before the Office.**

Election/Restriction

5. Applicant's election with traverse of Group II, claims 11 and 58-76 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the restriction is in error and that the Examiner has not shown that a serious burden would be required to examine the claims of Groups I and II. This is not persuasive because these inventions are distinct for the same reasons set forth in the action mailed 6/11/99, Paper No. 8, and have acquired a separate status in the art because of their recognized divergent subject matter as evidenced by the different subclasses. Art found in one may not necessarily reveal art in the other.

6. Group I, claims 1 and 10 are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to non-elected inventions.

7. As stated in Paper No. 8, election of a species is only applicable to Group I.

8. The requirement is still deemed proper and is therefore made FINAL.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R. § 1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R. § 1.48(b)* and by the fee required under *37 C.F.R. § 1.17(h)*.

Title

10. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Antibodies to cell cycle regulatory protein".

Specification

11. The use of the trademarks such as "pBLUEBAC," page 24, line 20, "pBLUESCRIPT," page 59, line 3, "FUJIX," page 59, line 7, "AXIOPHOT," page 59, line 33, and so on, of the specification has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is

permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

12. Each letter of the trademarks must be capitalized. *See MPEP 608.01(V)* and *Appendix 1.*

13. The disclosure is objected to because of the following minor informalities: On page 10, line 23, the word "uncouples" needs to be changed to "uncoupled", one page 59, line 31, the word "propidiem" needs to be changed to "propidium", and on page 59, line 33, the word "Axiphot", needs to be changed to "Axiophot". Appropriate action is required.

Claim Objections

14. Claim 11 is objected to for being dependent upon claim 10, which was not elected.

Claim Rejections - 35 U.S.C. § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 58-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 58 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation "at least four ankyrin-repeats". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.**

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

18. Claims 59, 61-64 and 66 rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

19. Claims 59 and 66 indefinite in the recitation of "stringent conditions". The term is not defined in the specification and it is therefore unclear under which conditions the Applicants intend the claimed polynucleotide sequences to hybridize. This rejection could be overcome by listing the conditions disclosed on page 17, line 34 and bridging over to page 18, line 5 into the claim.

Claim Rejections - 35 U.S.C. § 102

20. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

21. Claims 11, 58-61 and 65-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Skolnick, et al. *(US Patent No. 5,624,819).*

22. The '819 patent teaches an antibody (polyclonal antibody, as recited in claim *65*, col. 14, monoclonal antibody, col. 15, as recited in claim *61*) to a Cdk-binding protein encoded by a 947 bp sequence (for example, SEQ ID NO: 36; see col. 14, lines 28-63 and col. 15, lines 4-45). The identification of the taught MTS protein (p16) as interacting with Cdk, as recited in claim *11*, is taught in col. 8, line 61 and bridging over to col. 9, line 17 and col. 28, lines 2-34). The '819 patent teaches a 947 bp nucleotide (SEQ ID NO: 36) with a 94.9% sequence identity to SEQ ID NO: 1 of the instant application, a 751 bp sequence (SEQ ID NO: 15) with a 80.9% identity with SEQ ID NO: 3, a 395 bp nucleotide (SEQ ID NO: 25) with 98.5% identity over its entire length with SEQ ID NO: 5 of the instant application. Additionally, the '819 patent teaches a 156 amino acid sequence (SEQ ID NO: 2) with 98.6% identity with SEQ ID NO: 2 (see claim 1), and a 138 amino acid sequence (SEQ ID NO: 16) with 95.7% identity with SEQ ID NO: 4. The polypeptides of the '819 patent would inherently possess most of the same epitopes as the polypeptides disclosed herein, therefore, the antibodies of claims *11, 58, 60, 61, 65 and 67* would be encompassed by the teaching. Additionally, the nucleic acids disclosed in the '819 would inherently encode polypeptides with the same epitopes as disclosed herein and thus, the antibodies of claims *11, 58, 59, 61, 65 and 66* would be encompassed by the teaching. Therefore, the reference teachings anticipate the claimed invention.

23. Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by Booher, et al. *(Cell 58:485-497, 1989).*

24. Booher, et al. teach antibodies to a cell cycle regulatory protein (see Figure 1). Booher identifies the p63 protein as being involved in the regulation of the cell cycle (see the abstract). Therefore, the reference teaching anticipates the claimed invention.

Claim Rejections - 35 U.S.C. § 103

25. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 11 and 58-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skolnick, et al. *(US Patent No. 5,624,819).*

28. The '819 patent has been discussed supra. The '819 patent does not teach a kit comprising antibodies to the recited CCR protein. However, one of ordinary skill in the art would recognize that reagents in kit form, as recited in claims *68-76*, would be required to perform the screening assays taught in the '819 patent (see col. 28) using current clinical requirements for standardized reagents. Additionally, one of ordinary skill in the art would recognize the advantage of using antibodies in Fab or F(antibody')$_2$, form, as recited in claims *62 and 63*, for use in antibody staining techniques, wherein the absence of an Fc region reduces background, particularly if using FACS analysis. Also having a detectable label on the claimed antibody, as

claimed in claim *64*, would also reduce background if used in a direct antibody-binding detection procedure. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

29. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Mary B Tung

September 27, 1999
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

David A. Saunders

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